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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,217	02/14/2002	Shai N. Gozani	NEURO-NRO-008	8764

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02/23/2007

EXAMINER
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APANIUS, MICHAEL

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/075,217	Applicant(s) GOZANI ET AL.	
	Examiner Michael Apanius	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 24-36, 48-54 and 63-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-36, 48-54 and 63-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/27/2006</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This office action is in response to the amendment filed on 11/13/2006. The amendment is entered. The amendments to claims 24-28, 31, 35 and 36; the addition of new claims 63-75; and the cancellation of claims 3-15, 18-23, 37, 38, 40-42, 45-47 and 55-62. Currently, claims 24-36, 48-54 and 63-75 are pending. Upon further consideration, new rejections are set forth below.

#### ***Claim Objections***

2. Claim 74 is objected to because of the following informalities:
- a. At claim 74, "said at least one selected electrode" appears to be inconsistent with the language of claim 69 wherein at least one electrode is determined.
  - b. At claims 34, 53, 68 and 74, it is unclear how electrodes can have more energy at low frequencies. It appears that this limitation should be directed to the signals detected by the electrodes.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 24-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. At claim 24, step (e) is recited as part of the nerve conduction studies and provides an additional step of "performing said nerve conduction studies". However, since step (e) is part of the nerve conduction studies, the claim language appears to define a recursive loop wherein each time the method arrives at step (e), the method continues by returning to step (b). It is unclear how such a recursive method would be implemented. It appears that the claim language should be modified to clarify the relationship between steps (b)-(e).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 24, 26, 31, 35, 36, 48, 54, 63, 69 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosier (4,807,643) in view of Manoli (US 4,583,549) and Battmer (US 6,428,484).

8. Rosier discloses an apparatus for assessing physiological function in an individual comprising: a sensor, said sensor comprising: a stimulator (10) configured to generate a stimulus and a detector (24) comprising a plurality of electrodes each

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configured to detect a response signal generated in response to said stimulus. Rosier teaches performing nerve conduction studies (paragraph bridging columns 1 and 2) with at least one of the electrodes. The nerve conduction studies comprise processing and displaying the evoked responses.

9. In regards to claim 26, distal latency (column 2, line 3) is measured.

10. In regards to claim 31, the detected signal inherently comprises peripheral evoked potentials generated by the electrical stimulation.

11. In regards to claims 35 and 36, the detected signal over a motor point inherently comprises a compound muscle action potential generated by the electrical stimulation

12. In regards to the remaining claims, the limitations are similarly met as noted above.

13. However, Rosier does not expressly disclose a flexible connector that automatically positions the detector when the stimulator is positioned substantially adjacent to its anatomical site. Manoli teaches a flexible connecting means that automatically positions the other electrodes when one electrode is properly positioned for the purpose of providing an inexpensive, convenient and easy to use connector that ensures proper and automatic positioning of the electrodes (column 2, lines 22-29).

Manoli uses a flexible printed circuit board comprising multiple layers of material including a base layer in the form of a sheet of flexible plastic material (MYLAR) and a layer of conductive traces; and an electrical interface (20 in figure 5).

14. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a flexible circuit board as taught by Manoli to

automatically position the electrodes of Rosier in order to provide an inexpensive, convenient and easy to use connector that ensures proper and automatic positioning of the stimulating and detecting electrodes.

15. Furthermore, Rosier does not expressly disclose determining at least one electrode detecting a response signal characteristic of a second anatomical site.

16. Battmer teaches an electrode array and a multiplexer for the purpose of selecting electrodes that are best for sensing an evoked response characteristic of a nerve at a anatomical site (paragraph bridging columns 5 and 6).

17. It would have been obvious to one having ordinary skill in the art at the time of invention to have selected at least one electrode as taught by Battmer in the method and apparatus of Rosier as modified by Manoli in order to select the best electrode for sensing an evoked response.

18. Claims 25, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosier (4,807,643) as modified by Manoli (US 4,583,549) and Battmer (US 6,428,484), as applied to claims 24, 26, 31, 35, 36, 48, 54, 63, 69 and 75 above, and further in view of Applicant's admission of prior art. Rosier as modified by Manoli and Battmer does not expressly disclose measuring F-wave latency, sensory latency and sensory amplitude. However, Applicant discloses at page 13 of the specification that typical nerve conduction measurements include distal motor latency, sensory latency, and sensory amplitude. At page 25, line 21 of the specification, Applicant discloses that measurement of F-wave latency is also familiar to those knowledgeable in the art.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have measured F-wave latency, sensory latency and sensory amplitude as admitted prior art by the Applicant in the method of Rosier as modified by Manoli and Battmer because it is well-known and routine in the art to supplement one measurement with other measurements to help verify and provide further insight into the results of a study.

19. Claims 29, 32, 49, 50, 64, 66, 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosier (4,807,643) as modified by Manoli (US 4,583,549) and Battmer (US 6,428,484), as applied to claims 24, 26, 31, 35, 36, 48, 54, 63, 69 and 75 above, and further in view of Spitz et al. (US 5,215,100). Rosier as modified by Manoli and Battmer does not expressly disclose an amplitude comparison. Spitz teaches comparing maximal peak amplitudes for the purpose of determining if a test result is acceptable (column 14, lines 7-39). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have compared maximal peak amplitudes as taught by Spitz in the method and apparatus of Rosier as modified by Manoli and Battmer in order to determine if a test result is acceptable.

20. Claims 30, 33, 34, 51-53, 65, 67, 68, and 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosier (4,807,643) as modified by Manoli (US 4,583,549) and Battmer (US 6,428,484), as applied to claims 24, 26, 31, 35, 36, 48, 54, 63, 69 and 75 above, and further in view of Drongelen (US 6,224,549). Rosier as

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modified by Manoli and Battmer does not expressly disclose that the processing includes a frequency spectrum comparison or discrete Fourier transform analysis. Drongelen teaches using an FFT for frequency spectrum comparison (column 7, lines 46-49) for the purpose of monitoring, analyzing and displaying evoked potentials (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used an FFT for spectral analysis as taught by Drongelen in the method and apparatus of Rosier as modified by Manoli and Battmer in order to monitor, analyze, and display evoked potentials. In regards to claims 34, 53, 68 and 74, it is noted that electrodes used for obtaining evoked potentials will have more energy at low frequencies due to the nature of the measured signals.

### ***Conclusion***

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.



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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

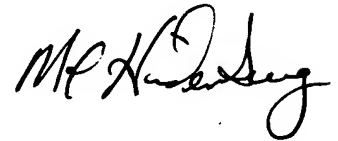
you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA

A handwritten signature in black ink, appearing to read "Mr. H. D. King". The signature is written in a cursive style with a large, stylized "K" and a long, sweeping underline.